

# Notice of Allowability

Application No.

10/724,274

Examiner

Lynn Bristol

Applicant(s)

RAMAKRISHNAN ET AL.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/11/07 and 5/10/07.
2. ☒ The allowed claim(s) is/are 51-53 and 58-63 (renumbered 1-9).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 3/15/07; 1/25/06; 7/27/05; 12/1/04; 6/28/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material LAB
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

  
**LARRY R. HELMS, PH.D.**  
**SUPERVISORY PATENT EXAMINER**

### **DETAILED ACTION**

1. Claims 51-53 and 58-63 are all the pending claims for this application.
2. Claims 51-63 were amended in the Response of 4/11/07 to introduce pharmaceutical composition claims (Claims 53, 55, 57 and 59) for the four respective antibody embodiments of Claims 51, 54, 56 and 58. Claims 51, 54, 56, 58, 60 and 62 were amended to clarify whether the respective antibody embodiment is a "chimeric antibody" (Claims 51, 54, 56, 58 and 60) or "humanized antibody" (Claim 62) in the Response of 4/11/07. Claims 54-57 were amended to recite sequences for SEQ ID NOS:16 and 18 (Claims 54-55) and SEQ ID NOS: 20 and 22 (Claims 56-57) that were non-elected, but reinstated in the Response of 4/11/07.
3. Claims 54-57 were cancelled in the Response of 5/10/07, and Claims 51-53 and 58-63 have been considered and entered.
4. The Examiner gratefully acknowledges the telephone interviews with Applicants representative on May 4, 10 and 18, 2007 in assisting to advance the instant claims to allowance.
5. Claims 51-53 and 58-63 are all the pending claims and are now in condition for allowance as set forth below.

### ***Information Disclosure Statement***

6. The international patent references and the non-patent literature reference cited in the IDS of 3/15/07 have been considered and entered.

**Rejections Withdrawn**

***35 USC § 112, first paragraph: written description***

7. The rejection of Claims 51-58 and 63 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement is withdrawn and moot for the cancellation of claims 54-57 in the Response of 5/10/07, and withdrawn for Claims 51-53, 58 and 63 in view of the amendment of Claims 51 and 58 to delete the limitations for "at least 95% identity" in the Response of 4/11/07. Applicant's comments on pp. 5-6 of the Response of 4/11/07 have been considered and entered.

***35 USC § 112, first paragraph: enablement***

8. The rejection of Claims 51-63 under 35 U.S.C. §112, first paragraph, as being non-enabled for chimeric or humanized antibodies that have heavy and light chains a) with at least 95% sequence identity to SEQ ID NOs: 1, 16, 20, 25, 28, and 31, as well as 7, 18, 22, 26, and 32, respectively (Claims 51-58 and 63); or b) "comprising" SEQ ID NOs: 1, 16, 20, 25, 28, and 31, as well as 7, 18, 22, 26, and 32, respectively (Claims 59-63) is withdrawn.

Claims 54-57 were amended to delete the limitation in the Response of 4/11/07 and the claims canceled in the amendment of 5/10/07.

The rejection is withdrawn for Claims 51-53, 58 and 63 in view of the amendment of Claims 51 and 58 to delete the limitations for "at least 95% identity" in the Response of 4/11/07. Applicant's comments on p. 6 of the Response of 4/11/07 have been considered and entered.

***Double Patenting***

9. The provisional rejection of Claims 51 and 54-63 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/830,956 ("956") is withdrawn in view of the cancellation of Claims 1-8 from the '956 application. Applicant's comments on p. 6 of the Response of 4/11/07 have been considered and entered.

10. The rejection of Claims 51 and 54-63 as not being patentably distinct from claims 1-8 of commonly assigned 10/830,956 is withdrawn in view of the cancellation of Claims 1-8 from the '956 application. Applicant's comments on p. 7 of the Response of 4/11/07 have been considered and entered.

***Examiner's Amendment***

11. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Adam K. Whiting on May 18, 2007.

Claim 52. (Currently Amended) The antibody of claim 51, where the source of the constant region is human IgG4 or IgG2M3.

The term "IgG2M3" was considered as raising an issue of new matter. The term did not appear *per se* in the specification. The only close reference appears to a laboratory name for the humanized M200 variable region cloned into a human IgG2 acceptor. See [198] of the specification for "HuM200-g2m3G" with description. Thus the meaning of the term "IgG2M3" is not well defined in the specification and is clearly distinct from an human IgG4 or an human IgG4 having an extra IgG2 constant domain insertion.

***Statement for Reasons for Allowance***

12. Claims 51-53 and 58-63 are found patentable for the following reasons. The claims are drawn to novel and nonobvious embodiments for the following antibodies:

Claims 51-53- M200 chimeric anti- $\alpha 5\beta 1$  integrin (mouse VH (SEQ ID NO: 1) and VL (SEQ ID NO:7)) human IgG (or IgG4) acceptor and pharmaceutical composition;

Claims 58-59- M200 chimeric anti- $\alpha 5\beta 1$  integrin (restriction enzyme site silenced to introduce different amino acid into mouse VH (SEQ ID NO:25) with VL (SEQ ID NO:26)) human IgG acceptor (or IgG4) and pharmaceutical composition;

Claims 60-61- Fab of chimeric antibody of Claims 58-59 (F200 of SEQ ID NO: 28 and 26) and pharmaceutical composition; and

Claims 62-63- fully humanized M200 inserted into human IgG4 (SEQ ID NO: 31 and 32) and pharmaceutical composition.

The claims are free of prior art as no other anti- $\alpha 5\beta 1$  integrin antibody was found to have these VH and VL domains.

Further, the recitation of "chimeric" or "humanized" for the respective antibodies is found to be consistent with the definition set forth in [075], p. 19 of the specification. The pharmaceutical composition claims, Claims 53, 59, 61 and 63, are supported by Examples 3-7 of the specification.

### ***Conclusion***

13. Claims 51-53 and 58-63 (renumbered as Claims 1-9) are allowed.
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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